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09/293,835

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JAMES C. KENNEDY

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06/02/2006

FOLEY & LARDNER
3000 K STREET NW
SUITE 500
WASHINGTON, DC 20007

EXAMINER

SHARAREH, SHAHNAM J

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 06/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/293,835

Applicant(s)

KENNEDY ET AL.

Examiner

Shahnam Sharareh

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9/22/2005, 12/01/2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 15, 28, 31-35, 52-54 and 56-63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 15, 28, 31-35, 52-54, 62-63 is/are rejected.
- 7) ☐ Claim(s) 56-61 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 10/27/2005.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

1. The amendment file on September 22, 2005 has been entered along with supplemental filings dated December 01, 2005. Claims 1, 15, 28, 31-35, 52-54, 56-63 are pending. Any rejection that is not addressed in this Office Action is considered moot in view of new grounds of rejection.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1, 15, 28, 31-35, 62-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levy et al US Patent 5,283,255 in view of Richter et al US Patent 5,705,518.

Levy teaches methods of treating infections comprising topically administering to a patient benzoporphyrins which are derivatives of protoporphyrin-IX. (see abstract) Levy further administers light to the site of interest where benzoporphyrin is applied. (see abstract, col 7, lines 3-35). Levy states that photodynamic treatment is effective for treating athlete's foot. Specifically, Levy indicates that his methodology can be employed for treating fungal infections (see col 19, line 4, and lines 19-24). It is established in the art that athlete's foot is caused by tinea pedis. Levy does not teach the use of 5-aminolevulinic acid as a photoactive agent for his methodology.

Richter teaches that photosensitive compounds include produgs such as 5-aminolevulinic acid which can produce drugs such as protoporphyrin (see col, lines 59-65; col 5, lines 61-67). The prodrug of Richter provides the same effect in vivo as other

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photosensitizing agents such as porphyrins and benzoporphyrins.(col 5, lines 61-col 6, line 5). In fact, Richter characterizes 5-aminolevulinic acid to functionally provide the same effects as benzoporphyrins. Richter teaches topical administration of the prodrug prior to employing photodynamic therapy (col 6, lines 8-20). Richter does not teach treatment of fungal skin conditions.

However, it would have been obvious to one of ordinary skill in the art at the time of invention to employ 5-aminolevulinic acid, taught by Richter, in methodology of Levy, because as taught by Richter, other functional equivalents such as aminolevulinic acid is expected to produce the same effects as protoporphyrin and benzoporphyrins. Since Levy teaches effectiveness of benzoporphyrins in treating skin infections caused by *tinea pedis*, the ordinary skill in the art would have had a reasonable expectation of success to achieve the same results when employing 5-aminolevulinic acid of Richter.

Response to Arguments

3. Applicant's arguments filed on September 22, 2005 have been considered but are only partially persuasive. Applicant's arguments are persuasive with respect to claims 56-61 because of the described source of infection.

4. Applicant first argues that Levy' relies on compounds that themselves are photoactive and therefore do not require conversion after being taken up by fungi. (see Arguments at page 8, 3rd para.). In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091,

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231 USPQ 375 (Fed. Cir. 1986). Here, the rejection is based on the combined teachings of references. Levy is used to show that photodynamic therapy is effective to treat athlete's foot. Richter on the underhand describes that for purposes of providing photodynamic therapy the agents used by Levy is art-recognized equivalents to 5-ALA. Thus, the combined teachings of the references meet all limitations of the rejected claims.

5. Applicant then argues that there is not likelihood of success that one could predict whether fungi, like animal cells, would take up protoporphyrin IX precursors. (see Arguments at page 9, 1st line of the page). In response to this line of argument Examiner states that Applicant is arguing unclaimed limitations. There is no active step requiring that any affected fungi has to reuptake the compounds instantly employed. Thus, applicant's arguments are not commensurate with the scope of the claims.

6. Applicant adds that in at least claims directed to methods of treating nail infections, the likelihood of success is lower because nail infections are notoriously difficult to treat. (see arguments at page 9, 2nd para.). First Examiner states that no claims are solely directed to methods of treating onychomycosis. Second, only claims 31, 52-54 mention the limitation of "onychomycosis." However, said claims are also directed to method of treating tinea unguium in alternative. Tinea unguium is a skin lesion. Therefore, Applicant's arguments are not entirely commensurate with the scope of the claims because none of such claims.

7. Nevertheless, with respect to treating tinea unguium Examiner states that obviousness does not require absolute predictability of success rather a reasonable

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expectation of success. Indeed, for many inventions that seem quite obvious, there is no absolute predictability of success until the invention is reduced to practice. There is always at least a possibility of unexpected results that would then provide an objective basis for showing that the invention, although apparently obvious, was in law nonobvious. *In re Longi*, 759 F.2d 887, 897, 225 USPQ 645, 651-52 (Fed. Cir. 1985); *In re Clinton*, 527 F.2d 1226, 1228, 188 USPQ 365, 367 (CCPA 1976). *In re Merck & Co.*, 800 F.2d at 1098, 231 USPQ at 380. Accordingly, claims 31, 52-54 stand rejected because there is at least a reasonable expectation of success for treating tinea unguium.

Allowable Subject Matter

8. Claims 56-61 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

9. No claims are allowed. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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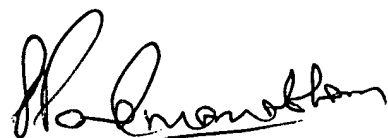
shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER